REMARKS

Claims 1 - 10, 12 - 14, 16 - 18, 20 and 21 are pending in the present application. In view of the following remarks, it is respectfully submitted that these claims are in condition for allowance.

Claims 1- 7, 10, 12 - 14, 16 and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,447,237 to Frisch et al. ("Frisch") in view of U.S. Patent No. 3,673,612 to Merrill et al. ("Merill"). *12/8/08 Office Action*, p. 2.

Claim 1 recites a pressure activated valve comprising "a valve housing defining a lumen for receiving bodily fluids therein" and "a flexible membrane disposed in the valve housing, *the flexible membrane including a slit extending therethrough so that the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen*" and "a first nonthrombogenic coating formed on fluid contacting surfaces of the flexible membrane, wherein *the nonthrombogenic coating includes hydrogel*."

The Examiner acknowledges that Frisch fails to disclose a nonthrombogenic coating including hyrdogel. It is respectfully submitted, however, that Frisch also fails to disclose a slitted membrane movable between an open and closed configuration based on a fluid pressure. Rather, Frisch discloses an implantable shunt device including a slit valve that is opened only by inserting a cannula-trocar assembly therethrough. Indeed, Frisch specifically teaches that the slit valve is pressurized to prevent it from opening based on a fluid pressure within the device.

In particular, Frisch describes a shunt device 1 formed of an elastomeric body containing a shunt path 3. *Frisch,* col. 4, ll. 1 - 4; *see* Fig. 1. Communication with the shunt path 3 is established by inserting a cannula-trocar assembly through a slit valve 20. *Id.* at col. 4, ll. 4 - 8; *see* Figs. 2- 4. The cannula-trocar assembly is inserted through the cannula-trocar assembly by

entering between opposed interior surfaces 21 of a sleeve or tube 22 defining a slit 23. *Id.* at col. 5, ll. 11 - 20. The Examiner contends that even though the slit 23 of Frisch is designed to open only upon insertion of the cannula-trocar assembly, any slit could be opened by a fluid pressure that is high enough. *11/27/07 Office Action*, p. 6. It is respectfully submitted that Frisch specifically teaches that the slit valve 20 should be pressurized to prevent even a high fluid pressure from opening the slit 23. Frisch teaches a pressurizing chamber 12 that extends from one side of the device 1 over the slit valve 20. *Id.* at col. 6, ll. 34 - 39. The pressurizing chamber is filled with a pressurizing yieldable material 25 to urge the interior surfaces 21 against one another, sealing the slit 23. *Id.* at col. 6, ll. 41 - 47. To safe guard against a high pressure of flow through the shunt path 3, Frisch teaches including another chamber 24 situated on an opposite side of the slot valve 20. *See Id.* at col. 7, ll. 41 - 58. Similarly to the pressurizing chamber 12, the chamber 24 is filled with a pressurizing yieldable material 26. *Id.* at col. 8, ll. 3 - 9. Frisch further acknowledges that the slit valve 20 can be made to seal against a variety of different fluid pressures. *Id.* at col. 9, ll. 16 - 21. Thus, it is respectfully submitted that the slit 23 cannot be opened via a fluid pressure. Furthermore, it is submitted that, although there is some fluid pressure which would force this slit open, this represents a failure of the device of Frisch. That is, because there is also a fluid pressure that would force open a steel door in a bulkhead of an ocean liner, that does not mean that this door is adapted to be moved between an open and a closed configuration based on a fluid pressure to which it is exposed. In the same manner as the valve of Frisch, such doors are designed to resist all the fluid pressures to which they are expected to be exposed.

Furthermore, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to have modified the device of Frisch to use hydrogel since hydrogel is not a known biologically active anticoagulant. Frisch discloses an implantable shunt that may include surfaces that are coated with a known anticoagulant such as heparin. *Frisch*, col. 12, ll. 18 - 24. It is respectfully submitted that biologically active coagulants such as heparin interfere with activations of various enzymes that otherwise result in the clotting of blood. Hydrogel, on

the other hand, is known for its lubricating properties, which reduces mechanical friction such that platelets are prevented from adhering to the coated surface. Thus, it is respectfully submitted that while hydrogel exhibits some anticoagulant properties, it is not a known anticoagulant as described in Frisch. Therefore, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to modify the device of Frisch to comprise a coating that includes hydrogel.

Accordingly, it is respectfully submitted that Frisch does not show or suggest a "*flexible membrane including a slit extending therethrough so that the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen*" and "a first nonthrombogenic coating formed on fluid contacting surfaces of the flexible membrane, wherein *the nonthrombogenic coating includes hydrogel*," as recited in claim 1.

It is respectfully submitted that Merrill does not cure the deficiencies of Frisch. Merrill discloses an anticoagulant such as heparin that may be bonded to membranes and solid polymeric surfaces containing hydroxyl groups such as hydrogel to create a nonthrombogenic material of a device. Merrill describes neither a valve nor *a coating* including hydrogel that may be applied to an existing surface of the device. Specifically, Merrill describes forming a nonthrombogenic polymer surface or membrane comprising a reaction product of heparin, a polymeric material and an aldehyde prepared with an acid catalyst. *Merrill*, col. 1, ll. 61 - 65. The reaction product comprises heparin covalently bonded to the polymeric material. *Id.* at col. 1, ll. 65 - 67. Thus, it is respectfully submitted that Merrill discloses formation of a material which is adapted to include an anticoagulant rather than a coating for use on existing surfaces of materials. Merrill specifies that certain polymeric materials, such as hydrogels, were evaluated because of its wide use in medical devices. *Id.* at col. 1, ll. 13 - 19. Indeed, Merrill states that hydrogels, which are contact-activated, would lead to clotting in less than half an hour if not treated with an anticoagulant such as heparin. *Id.* at col. 1, ll. 22 - 24. Thus, it is respectfully submitted that Merrill merely discloses the inclusion of hydrogel in a material that may be used in medical

devices, and does not show or suggest that a coating including hydrogel is used to treat an existing surface.

Accordingly, it is respectfully submitted that neither Frisch nor Merrill, either alone or in combination show or suggest a "*a first nonthrombogenic coating formed on fluid contacting surfaces of the flexible membrane, wherein the nonthrombogenic coating includes hydrogel*," as recited in claim 1. Thus, it is respectfully submitted that claim 1 is not rendered obvious by Frisch in view of Merrill and that the rejection of this claim should be withdrawn. Because claims 2 - 7 depend from and include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Similarly, claim 10 recites a dialysis catheter comprising "an elongated body having a proximal end connectable to a dialysis machine and a distal end adapted for insertion into a blood vessel" and "a lumen extending through the elongated body between the proximal and distal ends" in combination with "a valve disposed within the lumen for controlling a flow of blood therethrough, *the valve comprising a flexible membrane with a slit extending therethrough wherein, when a pressure above a predetermined threshold pressure is applied to the flexible membrane, the flexible membrane opens to allow flow through the slit*" and "*a nonthrombogenic coating applied to blood contacting surfaces of the valve, wherein the nonthrombogenic coating includes hydrogel.*"

For at least the same reasons as discussed above in regard to claim 1, it is respectfully submitted that claim 10 is not rendered obvious by Frisch in view of Merrill and that the rejection of this claim should be withdrawn. Because claims 12 and 13 depend from and include all of the limitations of claim 10, it is respectfully submitted that these claims are also allowable.

Claim 14 recites a medical device comprising "a lumen extending therethrough, a distal end of the device being adapted to fluidly connect the lumen to a blood vessel" and "a valve

disposed within the lumen for controlling a flow of blood therethrough, *wherein the valve is pressure activated to open when a fluid pressure within the lumen is at least a predetermined threshold value and remains sealed to prevent blood flow through the lumen when the fluid pressure within the lumen is below the predetermined threshold value*" in combination with *"a nonthrombogenic coating disposed on at least a portion of blood contacting surfaces of the device, wherein the nonthrombogenic coating includes hydrogel.*"

For at least the same reasons as discussed above in regard to claim 1, it is respectfully submitted that claim 14 is not rendered obvious by Frisch in view of Merrill and that the rejection of this claim should be withdrawn. Because claims 16 and 17 depend from and include all of the limitations of claim 14, it is respectfully submitted that these claims are also allowable.

Claims 8, 9, 18, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Frisch and Merrill in view of U.S. Patent No. 5,009,391 to Steigerwald ("Steigerwald"). *12/8/08 Office Action*, p. 3.

It is respectfully submitted that Steigerwald does not cure the deficiency of Frisch in view of Merrill, as discussed above in regard to claim 1. Steigerwald discloses a valve assembly that opens only when a catheter is inserted therethrough. Specifically, Steigerwald describes a valve assembly 20 including a first valve member 76 and a second valve member 82 arranged in a cavity 28. *Steigerwald*, col. 3, ll. 31 - 34. A catheter 56 is passed through the first and secondvalve members 76, 82 such that the valve members 76, 82 seal against the catheter 56, preventing the passage of blood therethrough. *Id.* at col. 4, ll. 23 - 28. Thus, it is respectfully submnitted that Steigerwald does not show or suggest that either of the valves 76, 82 are openable based on a fluid pressure.

Therefore, it is respectfully submitted that Steigerwald does not cure the deficiency of Merrill, in regard to claim 1. Since claims 8 and 9 depend from and include all of the limitations

of claim 1, it is respectfully submitted that these claims are allowable and that the rejection of this claim should be withdrawn.

Claim 18 recites a pressure activated valve comprising "a valve housing defining a lumen for receiving bodily fluids therein" and "a flexible member disposed in the valve housing, the flexible member comprising a plurality of flexible membranes stacked on one another, *each of the flexible membranes including at least one slit extending therethrough so that each flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen, wherein when all of the flexible membranes are moved to an open position, the flexible member is open to permit fluid flow through the housing*" in combination with "*a nonthrombogenic coating formed on fluid contacting surfaces of the flexible member, wherein the nonthrombogenic coating includes hydrogel.*"

As discussed above in regard to claims 8 and 9, it is respectfully submitted that Steigerwald does not cure the deficiency of Frisch in view of Merrill. Thus, for at least the same reasons as discussed above in regard to claim 1, it is respectfully submitted that claim 18 is not rendered obvious by Frisch in view of Merrill and in further view of Steigerwald and that the rejection of this claim should be withdrawn. Because claims 20 and 21 depend from and include all of the limitations of claim 18, it is respectfully submitted that these claims are also allowable.

Claims 18, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Steigerwald in view of Merrill. *12/8/08 Office Action*, p. 3.

It is respectfully submitted that Merrill does not cure the deficiencies of Steigerwald, as discussed above. The Examiner acknowledges that Steigerwald does not disclose a nonthrobogenic coating including hydrogel and cites Merrill to cure this deficiency. As discussed above, however, it is respectfully submitted that Steigerwald also does not show or suggest that a flexible membrane openable based on fluid pressure within the lumen.

For at least the same reasons as discussed above, it is respectfully submitted that Merrill does not cure the deficiencies of Steigerwald. Thus, it is respectfully submitted that claim 18 is not rendered obvious by Steigerwald in view of Merrill and that the rejection of this claim should be withdrawn. Because claims 20 and 21 depend from and include all of the limitations of claim 18, it is respectfully submitted that these claims are also allowable.

Claims 1 - 10, 12 - 14, 16 - 18, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Published Appln. No. 2004/0267185 to Weaver et al. ("Weaver") which has been issued as U.S. Patent No. 7,435,236 in view of Merrill. *12/8/08 Office Action*, p. 4.

It is respectfully submitted that Weaver is disqualified as a prior art reference under 35 U.S.C. § 103(c) since the invention of Weaver and the present application were commonly owned at the time of the invention. Weaver was filed on June 27, 2003 and the present application was filed on January 29, 2004. At the time of invention, Weaver and the present application were commonly owned by Scimed Life Systems, Inc. Currently, both Weaver and the present application are commonly owned by Navilyst Medical Inc. A Statement Under Rule 3.73(b) establishing a chain of title is enclosed herewith.

Claims 1- 10, 12 - 14, 16 - 18, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Published Appln. No. 2005/0048555 to Moorehead et al. ("Moorehead") in view of Merrill. *12/8/08 Office Action*, p. 5.

It is respectfully submitted that Moorehead is disqualified as a prior art reference under 35 U.S.C. § 103(c) since the invention of Moorehead and the present invention were commonly owned at the time of the invention. Moorehead was filed on August 29, 2003 and the present invention was filed on January 29, 2004. At the time of invention Weaver and the present invention were commonly owned by Scimed Life Systems, Inc. Currently, both Moorehead and the present invention are commonly owned by Navilyst Medical Inc. A Statement Under Rule

3.73(b) establishing a chain of title is enclosed herewith.

In light of the foregoing, Applicants respectfully submit that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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